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10/516,600	08/08/2005	Nicolas Aurio	N-32529A	7126
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NOVARTIS			KOSAR, AARON J	
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ONE HEALTH PLAZA 104/3			1651	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/516,600	<b>Applicant(s)</b> AURIO ET AL.
	<b>Examiner</b> AARON J. KOSAR	<b>Art Unit</b> 1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 14 December 2007.
- 2a) This action is FINAL.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 19-30,32,33,35-41 and 44-51 is/are pending in the application.
- 4a) Of the above claim(s) 19-21,29,38-41 and 44-51 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 22-28,30,32,33 and 35-37 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsman's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)  
 Paper No(s)/Mail Date 12/14/2007.
- 4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) Notice of Informal Patent Application
- 6) Other: \_\_\_\_\_.

**DETAILED ACTION**

***Response to Amendment***

Applicant's amendment and argument filed December 14, 2007 in response to the non-final rejection, are acknowledged and have been fully considered. Any rejection and/or objection not specifically addressed is herein withdrawn.

Applicant has amended the claims by canceling claims 31,34, 42, and 43 . Claims 19-30, 32, 33, 35-41, and 44-51 are pending, of which claims 19-21, 29, 38-41, and 44-51 are withdrawn as being directed towards non-elected inventions/species. Claims 22-28,30, 32, 33, and 35-37 are pending and have been examined on the merits.

***Claim Objections (Withdrawn)***

Applicant has argued that the objection of claim 27 should be withdrawn, because Applicant asserts that claim 27 further limits "gum"; however, while conceding that claim 27 limits the term "gum", the examiner maintains that claim 27 does not require selection of gum from the Markush group (*e.g.* does not recite that said fiber comprises gum wherein said gum is at least one of konjac gum, etc.). Therefore, selection of gum-free compositions (*i.e.* selection of mucilage, carrageenan, pectin, or  $\beta$ -glucan) is permitted by claim 27 and art drawn to said gum-free compositions would still anticipate the claim. In view of the above and upon further consideration the objection is hereby withdrawn.

***Claim Rejections - 35 USC § 112***

Applicant's amendment incorporating the subject matter of claim 31 into Claims 30, has rendered the rejection of the claims over the term "non-viscous", *moot*. Please note, however, the term "about 500 mPa•s", absent a definition as to the limits of "about" or an objective line

demarcating viscous versus non-viscous compositions viscosities, one may broadly and reasonably interpret "about" to embrace a broad range of viscosities, including compositions with viscosities orders of magnitude above 500 mPA•s.

**Claim Rejections - 35 USC § 102**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless —

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**Claims 22, 26-28, 30, and 35-37** are rejected under 35 U.S.C. 102(b) as being anticipated by BELL (A:PTO-892 3/26/07: US 6,210,686).

The claims are generally directed to a composition comprising one or more viscous soluble fibers and one or more viscosity-lowering proteins. The dependent claims are further drawn to the form of the composition (a drink) and the source of fiber and/or protein.

Bell teaches cholesterol level effecting composition (column 3, lines 50-62) that comprises fibers, including β-glucan (column 1, lines 44-58; column 3, lines 50-53), and protein, including whey protein, egg, and soy protein (column 5, lines 34-41). Bell also teaches that the composition includes a variety of product forms, including as a beverage or another oral composition (column 6, lines 41-44; column 7, line 26). Bell teaches that β-glucan from yeast has advantages over other forms of fiber; that yeast β-glucan functions to improve serum cholesterol levels (column 3 lines 50-62); and that the invention may also comprise individual or several ingredients including multiple proteins or fibers (column 5, lines 5-62).

Though Bell is silent regarding the elected species, Bell is applicable in demonstrating the unpatentability of the generic invention over the prior art.

**Claims 22, 23, 26-28, 30, and 35-37** are rejected under 35 U.S.C. 102(b) as being anticipated by JAUSSAN (AU 9873118 A).

The general teachings of the claims are above. Additionally, the dependent claims are drawn to proportions/ratios of components and the rheological properties (viscosity) of the composition.

Jaussan teaches a diabetes-treating composition comprising a protein (from milk, whey, casein, soy, rice, pea, and/or oat protein (page 4, lines 28-33)) and a viscous soluble fiber (guar gum, xanthan gum, gum Arabic, pectin, and/or  $\beta$ -glucan (¶5-6, page 3). Jaussan also teaches the composition has a viscosity of less than 500 mPa·s (1 Pa·s = 1 kg/m·s), including a composition having a viscosity of less than 0.04 kg/m·s, including 0.023 kg/m·s (¶3, page 6; ¶1, page 9; ¶1, page 13) and blending the composition with water to form a liquid composition (pages 6-7). Jaussan teaches a composition having the 1.0 g soluble fiber (0.5g pectin or gum arabic per 100ml sample (page 4, line 26; examples 1 and 2) and 3.8 g per 100 mL casein:soy protein (1:1) (examples 1 and 2). Jaussan thus teaches a composition comprising a soluble fiber: (soy) protein ratio of between 0.01:1 and 20:1, by teaching a ratio of 0.26:1 (w/w) ( $0.5:1.9 = 0.26:1$ ).

Though Jaussan is silent regarding the elected species of collagen, Jaussan is applicable in demonstrating the unpatentability of the generic invention over the prior art.

**Claims 22, 25-27, 30, 33, 35, and 36** are rejected under 35 U.S.C. 102(b) as being anticipated by SHIMIZU (US #6,589, 511).

Shimizu teaches an orally administered (periodontal) composition comprising viscosity-modulating agents including the viscosity-increasing ingredients collagen and guar gum, including combining one or more of the members including collagen and guar gum (claim 12;

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column 4, ¶1). Shimizu also teaches that the viscosity-increasing agent (which includes the member guar gum) is from 0.05% to 10% by weight (claim 2).

**Claims 22, 25-27, 30, 33, 35, and 36** are rejected under 35 U.S.C. 102(b) as being anticipated by LAUGHLIN (US #5,470,839).

Laughlin teaches an oral/enteric composition comprising guar (or gum arabic) and casein in the ratio of 0.15:1 (w/w) (7/45= 0.15/1)(example, column 6-7). Laughlin also teaches the composition has a viscosity of 90cPs max (example, column 6-7).

**Claims 22-28, 30, 32, 33, and 35-37** are rejected under 35 U.S.C. 102(b) as being anticipated by OHTA (EP 0323510).

OHTA teaches a composition comprising a protein and fiber, including casein and carageenan in liquid form (page 5; figures 5 and 8). Ohta teaches that liquid form is maintained in contact with gastric juices when protein in the composition is below half as that of the fiber component (abstract; page 5 ¶1-2). Ohta teaches modifying the ratios of fiber:protein or 0.1:1 through 2:1 (example 5, page 12) . OHTA also teaches modifying pH and temperature to affect viscosity, including effecting a viscosity below 100cPs, including less than 50cPs (figure 1). Ohta also teaches the formulation of the composition for food for diabetic/glucose-intolerant patients (page 18).

**Claims 22, 26-28, 30, and 35-37** are rejected under 35 U.S.C. 102(b) as being anticipated by HEATH (GB 2021948 A).

HEATH teaches a composition comprising guar gum and a protein coating including the use of casein, soy, or gluten in the coating (column 1; claims).

**(New) Claims 22-28, 30, 32, 33, and 35-37** are rejected under 35 U.S.C. 102(b) as being anticipated by MALLANGI (US 6355609 B1).

MALLANGI anticipates the claims by teaching a nutritional composition comprising fiber and protein, including guar gum and hydrolyzed whey protein (for example table 1; claims 1-23, especially 10, 18, 19, and (“enteral solution”) claim 20). Mallangi also teaches component proportions, that the compositions have viscosity, and that the compositions have use in nutritional/enteric compositions and in the range of guar gum:protein of approximately 0.01-10% ((0.25%-1.0%): (10-25%)) of the caloric content of the composition which is ( (column 3,*Detailed Description*, ¶3; Experiment No. 1; claims).

***Response to Arguments***

Applicant has argued that BELL, JAUSSAN, SHIMIZU, LAUGHLIN, OHTA, and HEATH (herein referred to collectively as “BELL, JAUSSAN, et al”) do not disclose an about 1-20kDa “moderately hydrolyzed protein”.

Applicant’s arguments have been fully considered; however, they have been found to be not persuasive, for the reasons of record and because Applicant discloses that “the hydrolysis..may occur *in vivo*, i.e. after ingestion of the composition” (Specification, page 4, lines 8-10). Accordingly, orally administered compositions would hydrolyze in the oral cavity/stomach and thus the prior art compositions are still deemed to anticipate the instant claims.

***Claim Rejections - 35 USC § 103 (Maintained)***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**Claims 22-28, 30, 32, 33, and 35-37** are rejected under 35 U.S.C. 103(a) as being

unpatentable over NAKAYAMA (US #6,287,623).

The general teachings of the claims are above.

NAKAYAMA teaches a drink composition comprising a protein and gelling agent (claims 9, 19, and 29), including a composition comprising casein and agar (example 8).

Nakayama teaches the food and drink composition having a viscosity of not greater than 20 centipoise (20cPs = 20mPa·s)(claims 9,19,29). Nakayama also teaches using gelling agents, including guar gum; varying/adding amounts of gelling agent; and using one or more proteins, including collagen/gelatin (columns 3, 6, and 7). Nakamaya also teaches modifying the composition based on the desired end product. In particular, Nakamaya teaches (a) optimizing the protein content to effect the desired smoothness of the product, including optimizing protein to be between 0.1 to 10% by weight and further optimizing to between 0.5 and 7% protein by weight (column 4, ¶4; column 6, ¶6); (b) optimizing the amount of gelling agent, including 0.1-1.0% (agar) by weight (column 6, ¶ 2); (c) direct measurement or, as needed to reduce viscosity in more viscous samples, dispersion with (500mL) water of a gelling-agent-containing drink compositions (column 7, ¶1-3); and (d) a ratio of fiber (gelling agent) to viscosity-lowering protein (protein) of 0.06:1 (see column 14, example 8: cascin/agar = 0.26/3.6 = 0.06/1).

To the extent that Nakayama is silent regarding the elected species combination of collagen and guar gum, it would have been obvious to one of skill to make a collagen-and-guar gum composition for the reasons below.

Please note that the terms that describe the species (e.g. guar gum) as a “gelling agent”, “viscosity-increasing agent”, “viscous, soluble fiber”, etc. presented below are relative descriptors of the intrinsic properties of each compound, such that, the compound (e.g. guar gum) is inseparable from its identity as a gelling agent, viscous soluble fiber, viscosity-increasing agent, etc.

Wherein Nakamaya teaches a liquid nutrient composition having protein and gelling agent comprising casein and agar (example 8), it would have been obvious to substitute the protein, casein, and gelling agent, agar, with collagen and guar gum, because Nakamaya teaches that any one or more proteins which may be used in food and drink may be used as the protein source, including collagen and/or casein(column 3, ¶1). Regarding the gelling agent, it would have been obvious to substitute agar with guar gum, because Nakamaya teaches that any suitable edible gelling agent may be used as the gelling agent source, including guar gum and/or agar (column 6, ¶3). One would have been motivated to substitute collagen and guar gum, because Nakamaya teaches a *finite* list of species of proteins/gelling agents, which includes collagen/guar gum, and because Nakamaya teaches that *any* one or more of these species may be used in the invention. One would have had a reasonable expectation of success in combining the compositions comprising collagen/guar gum, because Nakamaya teaches compositions comprising protein and gelling agent and because, absent evidence to the contrary, the success of

the combination of the two components, including collagen and guar gum depends merely upon the independent properties as protein and gelling agent.

To the extent the claims are also drawn to the elected species of guar gum:collagen ratios and viscosity of guar gum and collagen comprising compositions, though Nakamaya is silent regarding the ratio of guar gum:collagen or the viscosity of the combination with this species, Nakamaya teaches the general benefit of varying the composition components which includes the benefit of enhancing the texture, taste, and feel of the compositions. Varying the component proportions would necessarily affect the viscosity of the composition and Nakamaya further teaches the benefit of producing a product which has a viscosity less than 20cPs has a desirable smoothness (column 7, ¶ 2) and effecting a variety of viscosities (liquids, jellies, etc) in product preparations (see examples 1-8).

Nakamaya is relied upon for the reasons discussed above. If not expressly taught by Nakamaya, based upon the overall beneficial teaching provided by this reference with respect reagent/component ratios and viscosity in the manner disclosed therein, the adjustments of particular conventional working conditions (e.g., determining the optimal ratios of components to effect a desirable viscosity), is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

From the teachings of the reference, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Please note, since the Office does not have the facilities for examining and comparing Applicants' composition with the composition of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art. See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald*, 619 F.2d 67, 205 USPQ 594 (CCPA 1980), and "as a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith." *In re Brown*, 459 F.2d 531, 535, 173 USPQ 685, 688 (CCPA 1972).

***Response to Arguments***

Applicant has also argued that NAKAYAMA does not teach, suggest, or disclose all of the elements of the present claims and the reasons as argued for BELL, JAUSSAN, et al.

Applicant's arguments that the claims are not obvious over Nakayama are not persuasive, for the reasons of record in 35 USC 102, above. Additionally, the arguments of record drawn to NAKAYMA are maintained, because a reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the discussion of record (see above), the Examiner concludes that the subject matter defined by the instant claims, if not anticipatory, would have been obvious within the meaning of 35 USC 103(a). From the teachings of the reference of Nakayama, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to

one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AARON J. KOSAR whose telephone number is (571)270-3054. The examiner can normally be reached on Monday-Thursday, 7:30AM-5:00PM, ALT. Friday,EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Aaron Kosar/  
Examiner, Art Unit 1651

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